Docket No.: 208-015US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Fred Wehling et al.	Art Unit: 1618
Serial No.:	10/743,118	Examiner: Samala
Filed:	December 22, 2003	Confirmation No.: 7497
Title:	THERAPEUTIC EFFERVESCENT COMPOSITION	

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Appellants submit the following position in support of their Notice of Appeal, dated April 25, 2007, which was submitted in response to the outstanding Office Action dated December 22, 2006.

CERTIFICATE OF TRANSMISSION
I hereby certify under 37 CFR §1.8(a) that this correspondence is being electronically transmitted to the United States Patent and Trademark Office, by EFS-Web, on June 21, 2007.

Erin Margit Dajka
Signature
Erin Margit Dajka
Typed or Printed Name of Person Signing Certificate

Table of Contents

I. Real Party In Interest

The real party in interest is Amerilab Technologies, Inc.

II. Related Appeals and Interferences

There are no related appeals or interferences pending.

III. Status of Claims

Claims 1, 3 and 5-36 are rejected.

Claims 2 and 4 are cancelled.

Claims 1, 3 and 5-36 are on appeal.

IV. Status of Amendments

There are no unentered Amendments.

V. Summary of the Claimed Subject Matter

A summary of each independent claim and each dependent claim argued separately is provided below. The support listed for each claim is exemplary, as support for the claimed subject matter can be found in general throughout Appellants' Specification.

Claim 1 is directed to a tablet that includes an effervescent composition that includes from 0.5 % by weight to about 10 % by weight menthol, from 0.5 % by weight to about 10 % by weight eucalyptus oil, and an effervescent agent comprising an acid and a base, wherein the tablet dissolves in water having a temperature of at least 38°C to form a clear solution (Appellants' Specification, page 1, lines 24-26 and page 2, lines 1-2, 4-5).

Claim 8 depends from claim 1 and further specifies that the tablet has a hardness of at least 15 kilopounds (*Id.* at page 2, lines 7-8).

Claim 21 is directed to a tablet that includes an effervescent composition that includes from 0.5 % by weight to about 10 % by weight menthol, from 0.5 % by weight to about 10 % by weight eucalyptus oil, and an effervescent agent that includes an acid and a base, the tablet having a hardness of at least 10 kilopounds and dissolving in water having a temperature of about 38°C in less than 120 seconds (*Id.* at page 1, lines 24-26 and page 2, lines 1-2, 4-5, 7-8 and 10-11).

Claim 31 is directed to a carbonated mouthwash that includes water, menthol and eucalyptus oil (*Id.* at page 3, lines 3-4).

Claim 33 is directed to a method of using the tablet of claim 1, the method including dissolving the tablet of claim 1 in water to form a clear solution and inhaling vapors emitted by the solution (*Id.* at page 3, lines 8-10).

Claim 34 is directed to a method of using the tablet of claim 1, the method including dissolving the tablet of claim 1 in water to form a clear solution, and gargling with the solution (*Id.* at page 3, line 10).

Claim 36 is directed to the method of claim 33, wherein the water is boiling water (*Id.* at page 3, line 11-12).

VI. Grounds for Rejection to be Reviewed on Appeal

A. Whether claims 1, 3 and 5-36 are patentable under 35 U.S.C. § 103(a) over Gioffre et al. (U.S. 4,627,972) in view of Schobel et al. (U.S. 4,687,662) or Rockliffe et al. (U.S. 4,471,871) or Howard P. Andersen (U.S. 3,629,468)?

VII. Argument

Claims 1, 3 and 5-36 are patentable under 35 U.S.C. § 103 over Gioffre et al. (U.S. 4,627,972) in view of Schobel (U.S. 4,687,662) or Rockliffe et al. (U.S. 4,471,871) or Andersen (U.S. 3,629,468).

Claims 1, 3 and 5-36 stand rejected under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe et al. or Andersen.

Gioffre et al. disclose dentifrice compositions that provide an effervescent action and mechanical cleansing action when introduced to the oral cavity in the presence of water (Gioffre et al., col. 2, lines 10-13). Gioffre et al. disclose that the dentifrice composition includes an essentially anhydrous dentifrice base medium and an inorganic oxide material containing an effective amount of an adsorbed gas (*Id.*, col. 1, line 66-col. 2, line 2). Toothpaste is a dentifrice composition in the form of a paste.

Schobel discloses effervescent compositions in the form of tablets or powders that dissolve rapidly in cold water to yield an effervescent solution containing a completely dissolved therapeutic agent (Schobel, col. 1, lines 11-13). Schobel further describes a dissolution test that involves placing a tablet in 200 milliliters (mL) of water at 22°C and observing the various rates of dissolution of the tablet (*Id.*, col. 10, lines 63-64).

Rockliffe et al. disclose a method of packing dry-to-the-touch articles within a closed, moisture impervious container (Rockliffe et al., co. 1, lines 64-66). Rockliffe et al. further disclose the article can take the form of yarn, thread, woven or nonwoven fibrous sheet, block or sponge-like material, wool, a tablet or a powder (*Id.*, col. 5, lines 18-21). Rockliffe et al. explain the purpose of their article is to retain an included non-aqueous liquid in a matrix of polysaccharide, protein or a mixture thereof, until the article is moistened with water whereupon the non-aqueous liquid is released (*Id.*, col., 2, lines 16-21). Rockliffe et al. disclose a number of non-aqueous liquids (see, e.g., *Id.*, col., 3, line 40 – col., 4, line 38).

Andersen is directed to an effervescent tablet that can be placed directly in the mouth to provide a mouth wash (Andersen, col. 3, lines 5-7). Andersen discloses placing the tablet in contact with saliva in the mouth and adding a small amount of water to allow the effervescent reaction to commence (*Id.*, col.. 3, lines 3-7).

By way of background, Appellants have discovered how to form an effervescent tablet that includes both menthol and eucalyptus oil, and dissolves to a clear solution in a relatively short period of time. Oils are difficult to blend with traditional effervescent compositions and tend to stick to tablet punch presses. Forming tablets of effervescent compositions that include oils can lead to the release of chunks of the tablet as the tablet degrades in water (Appellants' Specification, page 1, lines 17-18). Many times the chunks do not fully dissolve (*Id.*, at lines 18-19). In addition, as the effervescent tablets degrade, an aesthetically undesirable residue (e.g., scum) can form on the surface of the water (*Id.*, at lines 19-20). The residue often includes oil, particulate, and, depending on the formulation of the effervescent composition, plant matter (*Id.*, at lines 19-21).

Claim 1 is directed to a tablet that includes an effervescent composition that includes from 0.5 % by weight to about 10 % by weight menthol, from 0.5 % by weight to about 10 % by weight eucalyptus oil, and an effervescent agent that includes an acid and a base, wherein the tablet dissolves in water having a temperature of at least 38°C to form a clear solution. Notwithstanding the assertions to the contrary in the December 22, 2006 Office action, Gioffre et al. do not teach an effervescent composition that includes "menthol, eucalyptus oil, anhydrous base medium and a gas containing inorganic oxide material." December 22nd Office action, page 3, first full paragraph. Gioffre et al. also do not teach a tablet that includes from 0.5 % by weight to about 10 % by weight menthol and from 0.5 % by weight to about 10 % by weight eucalyptus oil. Gioffre et al. also do not teach a tablet that dissolves in water having a temperature of at least 38°C to form a clear solution. Rather, Gioffre et al. disclose dentifrice compositions (e.g., toothpaste) and list a series of more than twenty flavoring agents and classes of flavoring agents that can be used in their dentifrice compositions (Gioffre et al., col. 4, lines 22-42). Although menthol and eucalyptus oil are included in this laundry list, Gioffre et al. do not teach or suggest including both menthol and eucalyptus oil in the same composition and further fail to teach including from 0.5 % by weight to about 10 % by weight menthol and from 0.5 % by weight to about 10 % by weight eucalyptus oil in the same composition, as required by claim 1. Gioffre et al. further fail to teach combining from 0.5 % by weight to about 10 % by weight menthol and from 0.5 % by weight to about 10 % by weight eucalyptus oil and forming the same into a tablet.

Gioffre et al. disclose that their dentifrice compositions include liquids and solids that may be formed into a creamy mass that is extrudable from a pressurized container (e.g., an aerosol) or a collapsible tube (e.g., an aluminum tube) (see, *Id.*, col. 5, line 32-col. 7, line 9). Gioffre et al. further disclose that in dental creams, the liquid vehicle will include glycerin, oils, propylene glycol, polyethylene glycol and mixtures thereof. (*Id.*, col. 5, lines 36-38). Gioffre et al. then disclose that their dentifrice composition can be in the form of chewable dental tablets (*Id.*, col. 7, lines 16-20). Gioffre et al. provide very little information about the chewable tablets other than to say that the components are proportioned similarly to the dental creams (*Id.*, col. 7, lines 16-23). Nothing in Gioffre et al. directs the skilled artisan to select menthol and eucalyptus oil for inclusion in their chewable tablet. Gioffre et al. also do not provide any reason that would motivate the skilled artisan to include both menthol and eucalyptus oil in their chewable tablet. Gioffre et al. further fail to teach or suggest including an effervescent agent that includes an acid and a base in their chewable tablet. Gioffre et al. actually teach away from such an agent. In particular, Gioffre et al. disclose that their dentifrice compositions are unique in providing effervescent action without the need of a chemical acid/base reaction (*Id.*, col. 2, lines 22-25). (Emphasis added.) Therefore the skilled artisan familiar with Gioffre et al. would have no reason to *sua sponte* add an acid and a base to the tablet of Gioffre et al. and would likely refrain from doing so.

Gioffre et al. also do not teach or suggest that it is important for their chewable dentifrice tablet to dissolve to a clear solution in water. The tablet of Gioffre et al. is described as being chewable and thus is administered by placing the tablet in the mouth and chewing. There is no inherent need for the chewable tablet of Gioffre et al. to dissolve to a clear solution. Therefore the skilled artisan would have no reason to formulate the dentifrice composition of Gioffre et al. into a tablet that dissolves to a clear solution in water. In light of the above, it cannot be disputed that Gioffre et al. fail to teach or suggest the tablet of claim 1.

Schobel does not cure the deficiencies of Gioffre et al. Appellants do not understand the manner in which Schobel is being combined with Gioffre et al. to render the tablet of claim 1 obvious. Appellants wish to note that they have previously expressly requested clarification as to the manner in which the cited references are being combined

so as to allegedly render the composition of claim 1 obvious. Such clarification has not been forth coming in a manner that is understandable. The Office actions seem to simply rely on the fact that the elements of claim 1 are mentioned in the various references. It is well established that although most inventions arise from a combination of elements that can be found in the prior art,

> [the] mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole. Rather to establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the ... [Examiner] must articulate the basis on which . . . [he or she] concludes that it would have been obvious to make the claimed invention. In practice, this requires that the ... [Examiner] explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.

In re Kahn 441 F.3d 977, 988 (Fed. Cir. 2006) citing *In re Rouffett*, 149 F.3d 1350 (Fed. Cir. 1998). (Citations omitted.) As further recognized by the United States Supreme Court, "'[R]ejections based on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR Int'l Co. v. Teleflex Inc.*, _____ U.S. _____ (2007) *quoting In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The Supreme Court has further held that an analysis demonstrating that there was a reason to combine the known elements in the fashion set forth in the claim must be explicitly set forth. See, e.g., *KSR Int'l Co. v. Telefelx Inc.*, _____ U.S. _____ (2007). It seems implicit that such an analysis must be set forth in a manner that is understandable by the reasonable Appellant. Appellants have not been able to ascertain the manner in which the references are being combined to arrive at the tablet of claim 1. "When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the Examiner to explain why the combination of the teachings is proper." See, MPEP 2143 *citing Ex parte Skinner*, 2 U.S.P.Q.2d 1788 (Bd. Pat. App. & Int. 1986). Since such explanation is not present in the record, Appellants submit that a *prima facie* case of obviousness has not been made. On this

basis alone, Appellants submit that the rejection of claims 1, 3 and 5-36 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen must be overruled.

Notwithstanding this lack of clarity, Appellants now attempt to address the secondary references cited in the rejection of claims 1, 3 and 5-36. To establish a *prima facie* case of obviousness, the Examiner must show, inter alia, a reason or "some objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art, would lead that individual to combine the relevant teachings of the references." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). "The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases, the nature of the problem to be solved." *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000). Combining prior art references without evidence of such a reason, suggestion, teaching or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability, which is the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). Here there is no such reason, teaching, suggestion or motivation.

As established above, Gioffre et al. are concerned with dentifrice compositions for cleansing teeth and the oral cavity (Gioffre et al., col. 1, lines 4-8). Schobel does not teach or suggest forming dentifrice compositions into tablets. Schobel also does not direct the skilled artisan to select both eucalyptus oil and menthol for inclusion in a single tablet. Schobel also does not teach or suggest how to formulate an oil, such as eucalyptus oil, into a tablet that dissolves to a clear solution. In addition, the function of Schobel's effervescent tablet is very different from that of the dentifrice of Gioffre et al. Schobel discusses the use of effervescent compositions as a means of administering solubilized therapeutic agents (Schobel, col. 1, lines 24-27). Schobel further refers to ingesting therapeutic agents (*Id.*, col. 1, lines 26-28). Schobel seeks to achieve a mechanism for solubilizing therapeutic agents in water (*see*, *Id.*, col. 2, lines 17-31). Gioffre et al. do not teach that their compositions are intended to be ingested, and Gioffre et al. are not concerned with administering therapeutic agents via a solution. Therefore, the skilled

artisan familiar with Gioffre et al. would have no reason to look to Schobel, would find Schobel to have no bearing on Gioffre et al., and further would find that Schobel provides no reason to modify the dentifrice of Gioffre et al. Accordingly, Appellants submit that the rejection of claim 1 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel is unwarranted and Appellants respectfully request that it be overruled.

The December 22nd Office action appears to rely on a theory of inherency in asserting that the combination of Gioffre et al. and Schobel renders obvious the tablet of claim 1. In particular, Appellants understand the December 22nd Office action to take the position that the composition of Gioffre et al. would inherently dissolve in water having a temperature of at least 38°C to form a clear solution. As a preliminary matter, it is undisputed that Gioffre et al. do not actually teach the composition of the tablet claim 1. This is evidenced by the fact that the rejection of claim 1 over Gioffre et al. is under 35 U.S.C. § 103 --not § 102. An obviousness rejection is predicated on the fact that no single prior art reference teaches the claimed invention. An obviousness rejection relies upon a reason, teaching, suggestion or motivation in a prior art reference or a combination of references to create a fictitious product. Therefore, in a rejection based on obviousness or a combination of two references, the product alleged to result from the combination never actually existed; such a nonexistent product could not have had any inherent properties. Because the tablet of claim 1 is not actually taught by Gioffre et al., the tablet never actually existed. Therefore, there is no actual tablet to which to ascribe any properties, inherent or otherwise. For this reason, inherency is not a proper basis for a rejection under 35 U.S.C. § 103. Rather, inherency is appropriate only in rejections based on anticipation under 35 U.S.C. § 102. *See, e.g., Trintec Industries, Inc. v. TOP U.S.A. Corp.,* 295 F.3d 1292, 1295 (Fed. Cir. 2002), *citing In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) ("Inherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art. ... [I]nherency does not embrace probabilities or possibilities.").

The secondary references of Rockliffe and Andersen do not cure the deficiencies of Gioffre et al. Accordingly, the rejection of claim 1 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen is further unwarranted for at least these additional reasons and Appellants respectfully request that it be overruled.

Claims 3, 5-20, 27-30 and 32-36 are distinguishable under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen for at least the same reasons set forth above in distinguishing claim 1.

Claims 8, 9, 23 and 24

Claims 8, 9, 23 and 24 are further distinguishable over the proposed combination of Gioffre et al. in view of Schobel or Rockliffe or Andersen for at least the following additional reasons. Claims 8 and 23 depend from claims 1 and 21, respectively, and further specify that the tablet has a hardness of at least 15 kilopounds. Claims 9 and 24 depend from claims 1 and 21, respectively, and further specify that the tablet has a hardness of at least 20 kilopounds. A specific tablet hardness is not a simple thing to achieve. It is not simply something that can be dialed into a tableting press. Rather, a tablet's hardness is a function of its composition. Not every composition can be tableted to any desired hardness. Gioffre et al. do not teach that tablet hardness is important for their chewable tablets. Gioffre et al. also do not teach a tablet that has any particular hardness --let alone the specific hardness required by claim 8. Gioffre et al. also fail to teach or suggest formulating a tablet that includes menthol and eucalyptus oil and that also exhibits a hardness of at least 15 kilopounds --or how to do so. Nothing in the record establishes anything to the contrary.

Schobel does not cure the deficiencies of Gioffre et al. Schobel does not teach or suggest formulating a composition that includes menthol, eucalyptus oil and an effervescent agent that includes an acid and a base into a tablet that exhibits a hardness of at least 15 kilopounds. The only mention in Schobel of hardness occurs in Example 1 wherein Schobel describes tableting a specific composition to a hardness of from 7-9 strong cobb harness units (Schobel, col. 8, line 25). The hardness of Schobel's tablet of Example 1 has no bearing on the patentability of claim 8. The hardness of the Schobel tablet does not constitute a teaching of a hardness of a tablet formed from any other composition --let alone a tablet that includes menthol, eucalyptus oil and an effervescent agent. Schobel also does not direct the skilled artisan to achieve such a hardness for a tablet made from any other formulation. Moreover, the disclosure of a hardness of from 7-9 strong cobb harness units does not constitute a teaching of a tablet hardness of at least

15 kilopounds. The relationship between strong-cobb hardness units (scu) and kilopounds (kp) is 1.4 scu =1 kp. Accordingly, a scu of 9 is equal to 6.4 kp. Thus, Schobel discloses that the tablet of Example 1 can have a hardness of from 5 kp to 6.4 kp. Schobel does not teach a tablet hardness of at least 15 kp.

The secondary references of Rockliffe and Andersen do not cure the deficiencies of Gioffre et al. Nothing in either Rockliffe or Andersen teaches or suggests a tablet exhibiting a hardness of at least 15 kilopounds. Nothing in the record establishes anything to the contrary. Thus, the proposed combination of Gioffre et al. and Schobel or Rockliffe or Andersen lacks a required element of the tablet of claim 8 . Accordingly, a *prima facie* case of the obviousness of claim 8 has not been made. Appellants submit, therefore, that the rejection of claim 8 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen is unwarranted and respectfully request that it be overruled.

Claims 9, 23 and 24 are further distinguishable under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen for at least the additional reasons set forth above with respect to claim 8.

Claims 21-26

Claim 21 is directed to a tablet that includes an effervescent composition that includes from 0.5 % by weight to about 10 % by weight menthol, from 0.5 % by weight to about 10 % by weight eucalyptus oil, and an effervescent agent that includes an acid and a base, the tablet having a hardness of at least 10 kilopounds and dissolving in water having a temperature of about 38°C in less than 120 seconds. The discussion set forth above regarding the deficiencies of Gioffre et al. in relation to claim 1 is incorporated herein. As set forth above, Gioffre et al. do not teach or suggest a tablet that includes menthol, eucalyptus oil and an effervescent agent that includes an acid and a base. Gioffre et al. also do not teach or suggest anything about the hardness of a tablet or a desirable tablet hardness. Gioffre et al. also do not teach or suggest that the dissolution time of a tablet is important.

Schobel does not cure the deficiencies of Gioffre et al. Schobel does not teach or suggest tableting dentifrices. Schobel also does not teach or suggest that tablet hardness

is important. Schobel also does not teach or suggest that it is important for a chewable dentifrice tablet to have a certain hardness. Schobel also does not teach or suggest selecting menthol, eucalyptus oil and an effervescent agent that includes an acid and a base for inclusion in a tablet and then formulating that tablet such that it exhibits a hardness of at least 10 kilopounds. Schobel also does not teach or suggest how to formulate a tablet of such a composition such that it will exhibit a hardness of at least 10 kilopounds and will dissolve in water in less than 120 seconds. As further demonstrated above, the only mention in Schobel of tablet hardness occurs in Example 1 wherein Schobel describes tableting a specific composition to a hardness of from 7-9 strong cobb harness units (i.e., from 5 kp to approximately 6.4 kp) (Schobel, col. 8, line 25). The hardness of Schobel's tablet of Example 1 has no bearing on the patentability of claim 21. Moreover, the disclosure of a hardness of from 7-9 strong cobb harness units (i.e., from 5 kp to approximately 6.4 kp) does not constitute a teaching of a tablet hardness of at least 15 kilopounds.

The secondary references of Rockliffe and Andersen do not cure the deficiencies of Gioffre et al. Nothing in either Rockliffe or Andersen teaches or suggests a tablet exhibiting a hardness of at least 15 kilopounds. Nothing in the record establishes anything to the contrary. Thus, the proposed combination of references lacks a required element of the tablet of claim 21. Accordingly, a *prima facie* case of obviousness of claim 21 has not been made. Appellants submit, therefore, that the rejection of claim 21 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen is cannot stand and Appellants respectfully request that it be overruled.

Claims 22-26 are distinguishable under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen for at least the same reasons set forth above in distinguishing claim 21.

Claim 31

Claim 31 is directed to a carbonated mouthwash that includes water, menthol, and eucalyptus oil. It is undisputed that neither Gioffre et al. nor Schobel nor Rockliffe et al. teach or suggest a mouthwash –let alone a mouthwash that includes menthol and eucalyptus oil. Appellants do not fully understand the basis for the conclusion in the

December 22nd Office Action that it would have been obvious to form the composition of Gioffre et al. into a mouthwash. It appears that the December 22nd Office action takes the position that an effervescent tablet that dissolves in water to produce a solution is uniquely desirable for use as a mouthwash and cites the passage at column 1, lines 24-33 of Andersen to support this position (see, December 22nd Office action, page 4, third full paragraph). Nothing in Andersen teaches or suggests that the fact that a tablet can dissolve in water to form a clear solution renders it uniquely suited for use as a mouthwash. Andersen also does not teach or suggest using all tablets as a mouthwash. To the contrary, Andersen explains that he has developed a particular formulation that forms a tablet that has a propensity to dissolve upon oral administration (Andersen, col. 2, lines 26-36). Andersen does not teach or suggest that all tablets, regardless of their composition, form a mouthwash or are suitable for forming a mouthwash. Andersen also does not teach or suggest how to modify the tablet of Gioffre et al. so as to cause it to form a mouthwash. Andersen also does not provide the skilled artisan with any reason to do so. The proposed combination thus fails to render obvious the mouthwash of claim 31. Appellants submit, therefore, that the rejection of claim 31 under 35 U.S.C. § 103 over Gioffre et al. in view of Andersen is unwarranted and respectfully request that it be overruled.

Claims 33 and 35

Claims 33 and 35 are further distinguishable over the proposed combination of Gioffre et al. in view of Schobel or Rockliffe or Andersen for at least the following additional reasons. Claim 33 is directed to a method of using the tablet of claim 1, where the method includes dissolving the tablet in water to form a clear solution and inhaling vapors emitted by the solution. Claim 35 depends from claim 33 and specifies that the water is at a temperature of 38°C. Neither Gioffre et al. nor Schobel nor Radcliffe nor Andersen teach or suggest dissolving a tablet in water to form a clear solution and inhaling vapors emitted by the solution. Nothing in the record establishes anything to the contrary. Appellants submit, therefore, that the record fails to establish a *prima facie* case of the obviousness of claim 33. Accordingly, the burden of persuasion has not shifted to Appellants and the rejection of claims 33 and 35 under 35 U.S.C. § 103 over

Gioffre et al. in view of Schobel or Rockliffe or Andersen cannot stand. Appellants respectfully request that the rejection be overruled.

Claim 36

Claim 36 is further distinguishable over the proposed combination of Gioffre et al. in view of Schobel or Rockliffe or Andersen for at least the following additional reasons. Claim 36 depends from claim 33 and further specifies that the water is boiling water. Neither Gioffre et al. nor Schobel nor Rockliffe nor Andersen teach or suggest dissolving a tablet in boiling water –let alone dissolving a tablet in boiling water to form a clear solution and then inhaling vapors emitted by the solution. Nothing in the record establishes anything to the contrary. Accordingly, the proposed combination of Gioffre et al. in view of Schobel or Rockliffe or Andersen fails to teach a required element of claim 36. Appellants submit, therefore, that the record fails to establish a *prima facie* case of the obviousness of claim 36. Accordingly, the burden of persuasion has not shifted to Appellants and the rejection of claim 36 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen cannot stand; Appellants respectfully request that the rejection be overruled.

Appellants now address the statements in the December 22nd Office action regarding the temperature of the water. There is no teaching or suggestion in any of the cited references of boiling water, a method that includes dissolving a tablet in boiling water, or a method that includes inhaling vapors; however, it appears that the Examiner may be relying on "official notice" of an alleged "well known fact" under MPEP 2144.03 to support the rejection of claim 36 over the proposed combination of Gioffre et al. and Schobel or Rockliffe or Andersen. Appellants note that official notice without documentary evidence to support an Examiner's conclusion of obviousness is permissible only in some circumstances (see MPEP 2144.03 A). In addition, official notice unsupported by documentary evidence should only be taken by the Examiner where the facts asserted to be well-known or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. See *Id.* ("The notice of facts beyond the record that may be taken by the Examiner must be 'capable of such instant and unquestionable demonstration as to defy dispute.'") As the MPEP

admonishes, "It is never appropriate to rely solely on 'common knowledge' in the art without evidentiary support in the record, as the principal evidence upon which a rejection . . . [is] based." MPEP 2144.03 A *citing In re Zurko*, 258 F.3d 1379, 1385 (Fed. Cir. 2001). Since there is no evidence of record that any of the cited references teach dissolving a tablet in boiling water, or a method that includes inhaling vapors, a *prima facie* case of obviousness of claim 36 has not been made. Accordingly, Appellants submit that the rejection of claim 36 under 35 U.S.C. § 103 over the proposed combination of Gioffre et al. in view of Schobel or Rockliffe or Andersen cannot stand and respectfully request that it be overruled.

Claim 34

Claim 34 is directed to a method of using the tablet of claim 1 that includes dissolving the tablet of claim 1 in water to form a clear solution and gargling with the solution. Gioffre et al. do not teach or suggest anything about gargling. As has been established above, Gioffre et al. also do not direct the skilled artisan to select menthol, to select eucalyptus oil, to select an effervescent agent that includes an acid and a base and then combine these ingredients in the form of a tablet. Gioffre et al. further fail to teach or suggest dissolving such a tablet in water.

Andersen does not cure the deficiencies of Gioffre et al. Andersen does not teach or suggest a tablet that includes menthol and eucalyptus oil. In addition, nothing in Andersen directs the skilled artisan to select menthol and eucalyptus oil and formulate the same into a tablet. Andersen also does not teach or suggest dissolving such a tablet in water to form a clear solution and then gargling with the clear solution. To the contrary, Andersen expressly states that no premixing of his tablet in a solution is necessary (Andersen, col. 4, lines 9-10). Andersen further explains that the necessary steps to using his tablet include "placing a tablet into the mouth, followed by an ounce of water. If no water is available, the user's saliva will do" (*Id.*, lines 10-13). Accordingly, the skilled artisan would have no reason to formulate a tablet that dissolves to a clear solution --let alone to formulate a tablet to include menthol and eucalyptus oil, dissolve it in water to form a clear solution and then to gargle with the same. For at least these additional

reasons claim 34 is distinguishable under 35 U.S.C. § 103 over the proposed combination of Gioffre et al. and Andersen; Appellants request that it be overruled.

It is undisputed that the secondary references of Schobel and Rockliffe also do not cure the deficiencies of Gioffre et al. Accordingly, the rejection of claim 34 under 35 U.S.C. § 103 over the proposed combination of Gioffre et al. and Schobel or Rockliffe is also unwarranted and Appellants request that it be overruled.

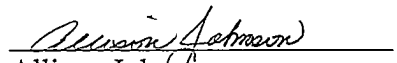
The claims now pending in the application are in condition for allowance and such action is respectfully requested. Appellants respectfully request that the Board overrule the rejections of record with instructions to the Examiner to pass the application to issue.

An Appendix of the Claims involved in the appeal is attached at Appendix A.

Please charge any fees owing or credit any over payments made to Deposit Account No. 501,171.

Respectfully submitted,

Date: June 21, 2007



Allison Johnson
Reg. No. 36, 173

Allison Johnson, P.A.
Lake Calhoun Executive Center
3033 Excelsior Blvd., Suite 467
Minneapolis, MN 55416
Telephone (612) 929-0700
Facsimile (612) 929-0706

CLAIMS APPENDIX

1. A tablet comprising an effervescent composition comprising:
from 0.5 % by weight to about 10 % by weight menthol;
from 0.5 % by weight to about 10 % by weight eucalyptus oil; and
an effervescent agent comprising an acid and a base;
wherein the tablet dissolves in water having a temperature of at least 38°C to form a clear solution.

3. The tablet of claim 1, wherein said composition comprises from 1 % by weight to about 5 % by weight menthol.

5. The tablet of claim 1, wherein said composition comprises from 1 % by weight to about 7 % by weight eucalyptus oil.

6. The tablet of claim 3, wherein said composition comprises from 1 % by weight to about 7 % by weight eucalyptus oil.

7. The tablet of claim 1 having a hardness of at least 5 kilopounds.

8. The tablet of claim 1 having a hardness of at least 15 kilopounds.

9. The tablet of claim 1 having a hardness of at least 20 kilopounds.

10. The tablet of claim 1, wherein said tablet dissolves in water having a temperature of about 38°C in less than 120 seconds.

11. The tablet of claim 1, wherein said tablet dissolves in water having a temperature of about 38°C in less than 100 seconds.

12. The tablet of claim 8, wherein said tablet dissolves in water having a temperature of about 38°C in less than 120 seconds.

13. The tablet of claim 8, wherein said tablet dissolves in water having a temperature of about 38°C in less than 100 seconds.

14. The tablet of claim 1, further comprising lubricant.

15. The tablet of claim 14, wherein said lubricant comprises sodium benzoate, polyethylene glycol, L-leucine, adipic acid, or a combination thereof.

16. The tablet of claim 1, further comprising magnesium oxide.

17. The tablet of claim 1, further comprising pigment.

18. The tablet of claim 1, further comprising flavor agent.

19. The tablet of claim 1, further comprising sweetening agent.

20. The tablet of claim 1, further comprising sorbitol.

21. A tablet comprising an effervescent composition comprising:
from 0.5 % by weight to about 10 % by weight menthol;
from 0.5 % by weight to about 10 % by weight eucalyptus oil; and
an effervescent agent comprising an acid and a base;
the tablet having a hardness of at least 10 kilopounds and dissolving in water having a temperature of about 38°C in less than 120 seconds.

22. The tablet of claim 21, wherein said tablet dissolves in water having a temperature of about 38°C in less than 100 seconds.

23. The tablet of claim 21 having a hardness of at least 15 kilopounds.

24. The tablet of claim 21 having a hardness of at least 20 kilopounds.

25. The tablet of claim 23, wherein said tablet dissolves in water having a temperature of about 38°C in less than 100 seconds.

26. The tablet of claim 24, wherein said tablet dissolves in water having a temperature of about 38°C in less than 100 seconds.

27. A package comprising
air tight sealed packaging; and
the tablet of claim 1 disposed in said sealed packaging.

28. The package of claim 27, wherein said package is free of puffing after storage at 45°C for 24 hours.

29. An effervescent composition comprising:
menthol;
eucalyptus oil; and
an effervescent agent comprising an acid and a base,
the composition dissolving in water having a temperature of about 38°C to form a clear solution.

30. A powder comprising the effervescent composition of claim 29.

31. A carbonated mouthwash comprising:
water;
menthol; and
eucalyptus oil.

32. A method of forming an aqueous effervescent composition, said method comprising dissolving the tablet of claim 1 in water.

33. A method of using the tablet of claim 1, said method comprising dissolving the tablet of claim 1 in water to form a clear solution; and inhaling vapors emitted by the solution.

34. A method of using the tablet of claim 1, said method comprising dissolving the tablet of claim 1 in water to form a clear solution; and gargling with said solution.

35. The method of claim 33, wherein said water is at a temperature of at least 38°C.

36. The method of claim 33, wherein said water is boiling water.

EVIDENCE APPENDIX

(NONE)

RELATED PROCEEDINGS APPENDIX
(NONE)